DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 22, 2015

LD Technology LLC
Albert Maarek
Quality Manager
100 N. Biscayne Blvd., Suite 502
Miami, Florida 33132

Re: K143152
Trade/Device Name: TM-ABI System
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, Pneumatic, Or Photoelectric Plethysmographs
Regulatory Class: Class II
Product Code: JOM
Dated: June 23, 2015
Received: June 24, 2015

Dear Albert Maarek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

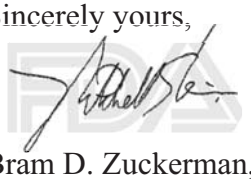
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k143152

Device Name: TM-ABI system

Indications for Use:

The TM-ABI system is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD).
TM-ABI system is intended for the rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI), and pulse volume recording (PVR) / volume plethysmography in adults. It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to the application of compression therapy.
TM-ABI system can be used on patients with unilateral lower limb amputation.
The TM-ABI System is intended to be used to spot-check patients. The TM-ABI provides information regarding patient risk. The physician has the responsibility of making proper judgments based on this information.
*Prescription Use: Federal law restricts the use of this device to sale by or on the order of a physician

Prescription Use X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Premarket Notification Number: date: May 27, 2015

510(k) Summary
TM-ABI device

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92

1. Submitter's Identification:
Manufacturer: L.D TECHNOLOGY
Address:
100 N.Biscayne Blvd, Suite 502
Miami, FL, 33132, USA
Tel: 305-379-9900
E mail: albert.ldteck@gmail.com

2. Device Name / Classification
Trade name: Patient monitor
Device Name and Model: TM-ABI system
Regulation number: 21CFR 870.2780
Product Code: JOM
Device Class: Class II
Classification Name: Hydraulic, pneumatic, or photoelectric plethysmograph
Classification Panel: Cardiology

3. Predicate legally marketed devices
Dopplex Ability K121108. Applicant: Huntleigh Healthcare Limited – Diagnostic Products Division. Product Code: JOM.

4. Device Description
TM-ABI System is a programmable electro medical system (PEMS). The system comprises:
- USB plug and play hardware.
- Software installed on a computer

It is intended to measure a patient's Ankle Brachial Pressure Index (ABPI) and Ankle brachial Index (ABI) and provides Pulse Volume Recording (PVR) / volume plethysmography.
This is done through an automated process.
The operator places the three color coded cuffs on the right or left arm, and on each ankle as described in the instructions for use, and connects to the device.
When connected, the operator clicks start on the software to begin measurement. The device will then automatically control the inflation & deflation of the cuffs and monitor variations in individual pressures to determine values to be used for the calculation of the ABI values for both the left and right of the patient.
TM-ABI uses pneumo-plethysmography in order to obtain physiologic measurements from patient’s limbs. Measurements are conducted as a single occurrence on the three limbs, eliminating any requirement to rest

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the patient between measurements.
The test period takes approximately 3 minutes.
The ABPI or ABI are calculated using the conventional algorithm:
The device measures systolic pressures on arm and 2 ankles and then calculates the ABIs as follows:

$$\text{Left ABI} = \frac{\text{Left ankle pressure}}{\text{Arm pressure}}$$

$$\text{Right ABI} = \frac{\text{Right ankle pressure}}{\text{Arm pressure}}$$

ABPI values, as well as the Pulse Volume recording (PVR), are displayed on the LCD, and on a software installed in a computer. The results are saved in a backup and can also be printed.

5. Intended use and indications for use
The TM-ABI system is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD).
TM-ABI system is intended for the rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI), and pulse volume recording (PVR) / volume plethysmography in adults. It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to the application of compression therapy.
TM-ABI system can be used on patients with unilateral lower limb amputation.
The TM-ABI System is intended to be used to spot-check patients. The TM-ABI provides information regarding patient risk. The physician has the responsibility of making proper judgments based on this information.
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6. Performances, technical specifications and materials
Performances
TM-ABI system measures simultaneous 3 blood pressure values using the oscillometic method.
It is portable medical device, powered by internal Li-Po battery and/or by an AC/DC converter.
It has two electrical inlets – power inlet and USB type B inlet, used for a connection with the software installed in a computer. TM-ABI system has three pressure inlets to connect three cuffs with specially designed connectors on both sides. These connectors are separated by indication color, also traceable on the colored hoses and colored cuffs.
The front panel foil indicates the device's name and manufacturer. It has an on/off button, start/stop/enter button, three function buttons, and LED power indicator. The color LCD screen is protected by a front panel foil.
The main purpose of the device is to measure ABPI, It also allows for checking measurement history.

Technical specifications i.e. table of comparison with the predicate device
Patient contact materials:
The materials in contact with the patient are the cuffs, tubes and bladders.
The Cuff material is nylon, and the Tube and Bladder material are PVC and latex free.
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7. Contra-indications

- **Patients undergoing external defibrillation.**
- **Patients connected to electronic life support devices, or any implanted electronic device.**
- **Bilateral mastectomy**
- Patients moving or undergoing long term monitoring.
- Do not use this device in the presence of:
  - Magnetic resonance imaging (MR or MRI) equipment. MRI equipment may deliver induced current to the device.
  - Strong electromagnetic sources, such as electro surgery equipment.
  - Computed Tomography (CT) equipment.
- Arterial catheters (access or therapy) on arm or leg or an arterio-venous (AV) fistula or shunt. The temporary interference of the blood flow could result in injury to the patient.
- Venous pulsations may cause erroneous reading in blood pressure (e.g. tricuspid valve regurgitation).
- Take caution with patients that have low perfusion. Using the blood pressure device may cause skin erosion and/or pressure necrosis.

8. Undesirable side effects:

No side effects or adverse reactions are known to date.

9. Substantial equivalence

Predicate legally marketed device: Dopplex Ability K121108. Applicant: Huntleigh Healthcare Limited – Diagnostic Products Division. Product Code: JOM.

Similarities

- ✓ The TM-ABI hardware has same intended use , same technology (oscillometric method) , and same performances and effectiveness (clinical study comparing to the standard Doppler probe method)

Differences:

Hardware Technological characteristics

- ✓ The TM-ABI uses 3 cuffs. The predicate device uses 4 cuffs
- ✓ The TM-ABI displays the Pulse volume/plethysmography from the cuffs during the process inflation/deflation. The predicate device displays the Pulse volume /Plethysmography from different cuffs at a constant pressure of 45 mmHg.

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Table of comparison

Information	TM-ABI	Dopplex Ability K121108
Intended use	The TM-ABI is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD). TM-ABI is intended for the rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI), and provides pulse volume recording (PVR) / volume plethysmography in adults. It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to the application of compression therapy. TM-ABI can be used on patients with unilateral lower limb amputation.	The Dopplex Ability is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD). Dopplex Ability is intended for rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI), and pulse volume recording (PVR) / volume plethysmography in adults. It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to the application of compression therapy. Dopplex Ability can be used on patients with unilateral lower limb amputation.
Dimensions/weight	width: 250 mm, height: 730mm, depth: 200 mm, weight: 0.60kg	Width: 260mm, height: 160mm, depth: 240mm weight: 3 kg
Display	4.3” color LCD screen with 16-bit color depth resolution: 480 x 272 pixels	B/W Analog display
Power Supply	Output: 5V DC/3.0A. Battery type: rechargeable lithium polymer AC/DC converter 5 V. Capacity: 2,300mAh, number of measurements per charge: 30	Output: 5VDC/3.0 A. Integral NiMH Battery Direct connection to the wall plug Capacity: 2,300 mAh Number of measurements per charge: 50
Applied parts in contact with the patient	3 cuffs, tubes and bladders	4 cuffs, tubes and bladders
Testing Bench	Type of protection against electric shock: Class II. BF Compliant with standards: 60601-1, 60601-1-2 80601-2-30.	Type of protection against electric shock: Class II. BF Compliant with standards: 60601-1, 60601-1-2 60601-2-30
Measurement types	Right and left Ankle brachial pressure index : Left ABI = Left ankle pressure / Arm pressure Right ABI = Right ankle pressure / Arm pressure	Right and left Ankle brachial pressure index Left ABI = Left ankle pressure / Highest Arm pressure Right ABI = Right ankle pressure / Highest Arm pressure

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Measurement ranges	Pressures range : Diastolic 40 to 180 mmHg Systolic 39 to 242 mmHg	Arm systolic pressures in the range 80 to 205mmHg and leg systolic pressures in the range 55 to 205mmHg.
Limit values of measurement errors	Ankle brachial pressure index: ± 0.1	Ankle brachial pressure index: ± 0.1
Cuffs inflation and deflation	Automatic inflation using an air pump and deflation using an electromagnetic valve.	Automatic inflation using an air pump and deflation using an electromagnetic valve.
Pulse Volume /Plethysmography	Pneumo-plethysmography method using the cuffs measuring the blood pressure values : Plethysmography displayed at the inflammation and deflation pressure	Pneumo-plethysmography method using additional cuffs at constant pressure of 45 mmHg.
Temperature and humidity range	working environment: 10 to 40°C, 30 to 85% relative air humidity, IPX0 protection, transport and storage: 0 to 60°C, up to 85% relative air humidity.	working environment: 10 to 40°C, 30 to 85% relative air humidity, IPX0 protection, transport and storage: 0 to 60°C, up to 85% relative air humidity.
Target population	Adult	Adult
Where used	Clinical environment	Clinical environment
PC Data transmission	USB	USB
ABI results: Coefficient of correlation r with the standard Doppler probe method	r= 0.88	r=0.89

10. Performances and Effectiveness

CRC (Cyclic redundancy check) Coding was performing to demonstrate the software performance to accurately capture, store, and analyze the data measured by the hardware.

Testing comprises:

1. Calibration tests
2. Software verification (SRS/SDS/STD/STR)
3. Clinical Study comparing the device results and standard Doppler method results to assess the Ankle Brachial Index.

The following facts:

- ✓ The TM-ABI use 3 cuffs and therefore 3 blood pressure measurements at same time and the predicate device use 4 cuffs and therefore 4 blood pressure measurements in same time.

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- ✓ TM-ABI uses the same cuffs during the inflation/deflation to display the Pulse volume , and the predicate device use different cuffs at constant pressure of 45 mmHg

Do not affect the performances and the effectiveness of the TM-ABI system comparing to the predicate device as shown by the clinical studies of TM-ABI and the predicate device versus.
The standard Doppler probe method. In addition, the manufacturer of the predicate device states: "The pulse volume recording / Volume plethysmography can be used as an adjunct to the Ankle Brachial Index (ABI), and an alternative to Doppler waveforms." And therefore, it is not the primary intended use of the device which is a rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI).

11. General Safety Concerns

The laboratory tests reports of the TM-ABI System have demonstrated the general safety of the system compared to the legally marketed predicate device.
NOTES! The performed laboratory tests are updated compared to the predicate device.

12. Standards

- ✓ IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Third Edition December 2006
- ✓ IEC60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. Third Edition 05/17/2007
- ✓ IEC 80601-2-30: Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers. 10/31/2010 Second Edition
- ✓ Guidance for: Industry; FDA staff; and Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005
- ✓ ISO 14971: Medical devices — Application of risk management to medical devices. March 01 2007

Conclusion
TM-ABI system is equivalent in performance, technology, safety and efficacy to the legally marketed predicate device.
Signature:

Albert MAAREK

Premarket notification [510K] Number: k143152